

## CP 2.6 Specimens Collected Under 12 Hours of Age (Early Specimen)

### POLICY:

All specimens collected early (<12 hours of age) and those with missing or erroneous information (date and time of birth and/or date and time of collection) such that age at collection cannot be determined require follow up by the ASCs.

1. Coordinators and Program Specialists may follow up early collections in NICU and Normal Newborn Nursery; Community Liaisons may follow up early collections in the Regular Newborn Nursery only.
2. If the specimen is confirmed to be collected at less than 12 hours of age or if the NBS provider cannot provide missing data needed to calculate a baby's age at collection, a second specimen will be required and will be sent to the appropriate NAPS laboratory for testing.
3. The result mailer for the initial specimen (collected at < 12 hours of age) will list all the test results. If the screen was negative for all the tests, the mailer will have a statement, which says, *"This specimen was reported to be collected at less than 12 hours of age. Testing of amino acid disorders at less than 12 hours of age may not be reliable for detecting amino acid disorders. Another specimen must be collected on this infant."*
4. ***If there is a positive result for any of the amino acid disorders on the initial early-collected specimen***, the above statement will **not** appear. A positive will be followed up per the MS/MS Follow-up Protocol. The ASC staff will need to convey to Metabolic Center staff following the newborn that the NBS was collected at < 12 hours of age and that the NBS needs to be repeated as part of the follow-up.
5. The Result Mailer will be held for three (3) business days before being sent in order to give the ASC staff time to verify dates/times and make changes to the case as necessary. After that period, the mailer will be sent with the information that is in the computer database (SIS) at that time. If verification of age and collection time are made after the three days and the baby was  $\geq$  12 hours of age at time of specimen collection, the ASC will need to generate a modified mailer to be sent to the newborn's physician and the hospital.
6. Specimens collected at less than 12 hours of age will be billed to hospitals. The repeat specimens WILL NOT be billed.
7. The results for specimens collected at less than 12 hours will be flagged by SIS so that GDSP evaluation staff will easily be able to distinguish these records. Repeat specimens will be linked by SIS to the early initial specimens.

## 2.6 (Cont'd.) Specimens Collected Under 12 Hours of Age

### PROTOCOL:

RESP. PERSON	ACTION
Perinatal Facility Staff	<ul style="list-style-type: none"> <li>• If baby is to be discharged prior to 12 hours of age for any reason, collects blood specimen as close to the time of discharge as possible.</li> <li>• If newborn is not being transferred to another hospital:               <ol style="list-style-type: none"> <li>1. Arranges for the baby to return and a repeat specimen to be collected between 24 hours and 6 days of age at health facility/hospital.</li> <li>2. Informs parent(s)/legal guardian(s) of the requirement for a repeat test and gives instructions for returning to hospital for testing.</li> <li>3. Provides parent with brochure entitled <i>Newborn Screening for Babies Leaving the Hospital Prior to 12 Hours of Age</i> (available on NBS website) Places copy in newborn's medical record and provides parent(s)/legal guardian(s) with copy of form</li> <li>4. Documents discharge and information given to parent(s)/legal guardian(s) in baby's medical record.</li> </ol> </li> </ul>
ASC Community Liaison/ Program Specialist/ Coordinator	<ul style="list-style-type: none"> <li>• Reviews daily NBS Headline Cases and reviews those cases flagged as collected &lt; 12 hours of age with no positive results, as well as positives to determine if they were collected early.</li> <li>• Contacts the hospital that drew the specimen to verify date &amp; time of birth and collection.</li> <li>• If early collection is confirmed or if hospital cannot confirm age of baby at time of collection, instructs hospital to obtain second specimen and send to appropriate NAPS laboratory.</li> <li>• If TRF indicates RBC transfusion before collection, notifies provider of the option available for DNA testing to rule out a hemoglobinopathy (See Section 3.213.10).</li> <li>• Contacts family when necessary to obtain specimen.</li> <li>• For those specimens determined to be collected at greater than 12 hours, makes changes to the SIS record (Case Summary) by changing/adding appropriate date/time.</li> <li>• Information is entered via the tracking events and case notes. Once errors are corrected, the case will drop off Headline Case list. If changes are made after mailer has already been sent, ASC will need to generate a modified mailer to be sent to the primary care provider and the hospital.</li> <li>• If baby received RBC transfusion after early collection, the repeat screen must be collected at least 24 hours after the last transfusion was completed.</li> </ul>